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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,259	10/17/2001	Bo Qiu	271/289	8229
34055	7590	10/18/2004	EXAMINER	
PERKINS COIE LLP POST OFFICE BOX 1208 SEATTLE, WA 98111-1208			SWARTZ, RODNEY P	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 10/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/982,259	QIU ET AL.
	Examiner Rodney P. Swartz, Ph.D.	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 18May2004.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 14, 15, 46-70 is/are pending in the application.
 4a) Of the above claim(s) 58-60 and 64-70 is/are withdrawn from consideration.
 5) Claim(s) 14 and 15 is/are allowed.
 6) Claim(s) 46-57, 61-63 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) 14, 15 and 46-70 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/04, 8/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's Response to Office Action, received 18May2004, is acknowledged. Claims 14 and 15 have been amended. Claims 1-13 and 16-45 have been cancelled. New claims 46-70 have been entered.

Newly submitted claims 58-60 and 64-70 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 58-60 and 64-70 are drawn to a method of identifying an antibody in a fluid sample. This invention would have been restricted out from the composition claims originally presented because the originally presented composition claims and the newly added method claims are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide can be utilized *in vivo* for immunization against infection with *Borrelia*.

Since applicant has received an action on the merits for the originally presented invention, a composition, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 58-60 and 64-70 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. Claims 14, 15, 46-57, and 61-63 are pending and under consideration.

Rejections Moot/Withdrawn

3. The objection to claims 29 and 30 under 37 CFR 1.75(c), is moot in light of the cancellation of the claims.

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4. The rejection of claims 16, 29, and 30 under 35 U.S.C. 112, first paragraph, is moot in light of the cancellation of the claims.

5. The rejection of claims 14 and 15 for insufficient antecedent basis, is withdrawn in light of the amendment of the claims.

6. The provisional rejection of claims 1, 16, 29, and 30 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim1, 14, and 15 of copending Application No. 09/982,264, is moot in light of the cancellation of the claims.

7. The provisional rejection of claims 14 and 15 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim1, 14, and 15 of copending Application No. 09/982,264, is withdrawn in light of amendments of the instant claims and amendments of claim of copending Application No. 09/982,264.

New Rejections Necessitated by Amendment

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 61-63 are rejected under 35 U.S.C. 112, second paragraph, because claims 61 and 62 recite the limitation "reporter moiety". There is insufficient antecedent basis for this limitation in the claim because claims 61 and 62 are dependent from claim 58 which does not recite "reporter moiety". Claim 63 depends from claim 62 and also recites "reporter moiety".

In addition, claim 58 is a method claim while claims 61-63 are products.

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11. Claims 47, 48, 50-57, and 61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 47, it is unclear how a polypeptide comprises a composition. Usually a composition comprises a polypeptide.

In claims 48 and 50-57, it is unclear how a polypeptide comprises a kit. Usually a kit comprises a polypeptide.

Claim 61 recites the “epitope polypeptide” of claim 58 wherein the “epitope” is attached “both” to the reporter moiety directly “and” to the reporter moiety where the epitope is attached to a carrier at a “first” location, and the carrier is attached at a reporter moiety at a “second” location. It is unclear from this recitation what is the attachment and structure of the polypeptide/reporter/carrier, and is the attachment through the entire polypeptide or only an “epitope”.

12. Claim 49 is rejected under 35 U.S.C. 112, second paragraph, lack of antecedent basis. Claim 49 depends from claim 46 and recites “wherein detecting Lyme’s disease in a subject”. There is insufficient antecedent basis for this limitation in the claim because claim 46 does not recite “detecting Lyme’s disease in a subject”, only that the polypeptide binds to an antibody found in a subject with Lyme disease.

13. Claim 46-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 46 is drawn to a polypeptide comprising SEQ ID NO:7. The use of open language “comprising” encompasses polypeptides with unknown regions of undetermined length on

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either end of SEQ ID NO:7. Therefore, it is unclear by the recitation "where the polypeptide binds to an antibody found in a subject with Lyme disease" whether said antibody must bind to SEQ ID NO:7 only, or may bind to the unknown regions. Claims 47-57 depend from claim 46, but do not clarify the indefiniteness.

Conclusion

14. Claims 46-57 and 61-63 are rejected. Claims 14 and 15 appear to be allowable.
15. Applicant's amendment adding new claims necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claim 58-60 and 64-70 drawn to a nonelected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571)

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272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

October 13, 2004